REMARKS/ARGUMENTS

In this response, no claims are being amended, added, or canceled. Thus, claims 1-48 and 80-100 remain pending in the application. Reconsideration and allowance of this application is respectfully requested in view of the remarks below.

Claim Rejections – Obviousness-Type Double Patenting

The Office Action provisionally rejected claims 1-48 and 80-100 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-102 of copending application no. 10/643,016 (attorney docket no. GUID.088PA) in view of U.S. Patent 6,928,324 (Park et al.).

In response, Applicants respectfully request that this rejection be held in abeyance until allowable subject matter has been acknowledged by the Examiner in view of the provisional nature of the rejection and the policies set forth in MPEP § 804(I)(B)(1).

Claim Rejections – § 112

The Office Action rejected claims 1-48 and 80-100 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection centered on the use of the phrase "estimating an accuracy of the disordered breathing prediction", which appears in each of independent claims 1, 80, and 100. Applicants respectfully traverse.

Legal Standard. In order to satisfy the written description requirement of 35 U.S.C. §112, first paragraph, *in haec verba* support for claimed subject matter is not required. See *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Rather, under the written description requirement, the disclosure "must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention." *Crown Operations International v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). The requirement is satisfied by the patentee's disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. See *Id.* Stated differently, one skilled in the art, reading the original disclosure, "must

reasonably discern the limitation at issue in the claims." *Id.* With this as the standard for compliance with the first paragraph of §112, the as-filed application can be seen to clearly support the disputed language.

The Examiner is correct in pointing out that the specification provides support for "estimating an accuracy of prediction criteria" – the specification certainly provides word-for-word support for such a phrase. But the specification also provides support for the objected-to phrase "estimating an accuracy of the disordered breathing prediction", because one skilled in the art, reading the original disclosure, can reasonably discern this limitation. The person of ordinary skill can reasonably discern this using the following line of reasoning:

1. the original specification teaches that the prediction of disordered breathing ("**disordered breathing prediction**") is accomplished using the **prediction criteria**, in at least some embodiments (see e.g. p. 21, lines 21-22, p. 22, line 25 – p. 23, line 2; p. 25, lines 14-16);
2. the original specification teaches that the **accuracy** of the **disordered breathing prediction** is dependent upon the **accuracy** of the **prediction criteria** (see e.g. p. 29, lines 21-25, which explains how more stringent condition levels for the criteria set produce a more accurate prediction of disordered breathing);
3. the original specification teaches how to **estimate an accuracy of the prediction criteria** (see e.g. p. 25, lines 20-28, or p. 26, lines 1-7, or p. 27, lines 3-12);
4. from items (2) and (3), the person of ordinary skill would understand that the **estimate of the accuracy of the prediction criteria** is indicative and/or representative of an **estimate of the accuracy of the disordered breathing prediction**.

The person of ordinary skill would thus reasonably ascertain from the as-filed application "estimating an accuracy of the disordered breathing prediction" as currently claimed. Withdrawal of the rejection under §112 is respectfully requested.

Claim Rejections – § 103

The Office Action rejected claims 1-9, 14-18, 20, 22-27, 30-45, 47-48, 80-83, 85-86, 88-96, 98, and 100 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,126,611 (Bourgeois et al.), hereinafter "Bourgeois", in view of U.S. Patent 6,366,813 (DiLorenzo). The Office Action states, among other things, that "[s]ince Bourgeois et al. detects an indication of the onset of sleep apnea, Bourgeois et al. predicts disordered breathing." This rejection cannot be sustained.

The Office Action provides no response to, and not even an acknowledgment of, Applicants' argument in their October 4, 2007 Response that since *onset* refers to "the beginning of something", and since *predicting* refers to "say[ing] or estimat[ing] that a specified thing will happen in the future, Bourgeois' disclosure of detecting the *onset* of sleep apnea in no way teaches "predicting disordered breathing" as set forth in claim 1, for example. Bourgeois' disclosure of detecting an episode of sleep apnea once it has already begun does not constitute predicting the occurrence of sleep apnea. By analogy, if someone were to detect the *onset* of a rainstorm by feeling raindrops, we would not say that person has predicted the rainstorm.

Applicants maintain this argument and traverse the Examiner's contention that Bourgeois teaches "predicting disordered breathing" (claim 1), or a prediction engine "configured to predict disordered breathing" (claim 80), or "means for predicting disordered breathing" (claim 100). DiLorenzo does not remedy these shortcomings of Bourgeois, and therefore the rejection of claims 1, 80, 100, and their respective dependent claims 2-9, 14-18, 20, 22-27, 30-45, 47-48, 81-83, 85-86, 88-96, and 98 under § 103 based on the combination of Bourgeois and DiLorenzo cannot be sustained and should be withdrawn.

The Office Action also asserts that "DiLorenzo teaches that it is known to estimate, or model, of fluctuation may be based upon a combination of preset, learned, and real-time sensed parameters as set forth in column 42, lines 50-60, for the purpose of prediction of future symptomatology, cognitive and neuromotor functionality, and treatment magnitude requirements", and that it would have been obvious "to have modified the predictive criteria

as taught by Bourgeois et al. with the estimation of the accuracy of predictive criteria as taught by DiLorenzo, in order to provide the predictable results of determine relevant data, prevent outliers and create accurate predictions."

Applicants strongly disagree with this conclusory argument. It would not have been obvious to modify predictive criteria taught by Bourgeois at least because Bourgeois has nothing to say about the prediction of disordered breathing, as explained above. Furthermore, the Office Action fails to explain how DiLorenzo's prediction of future fluctuations based on prior characterization of circadian fluctuation in symptomatology "that is, tremor magnitude for deep brain stimulation or level of depression for stimulation of other sites including locus cerulius" (col. 42, lines 37-41), in an intracranial stimulation device (col. 1, lines 16-20), would be expected to have any applicability whatsoever to the pacemaker system discussed in Bourgeois, much less how it would be expected to "determine relevant data", "prevent outliers", or "create accurate predictions" in Bourgeois' system. No convincing rationale has been given for the proposed combination, and the rejection of claims 1-9, 14-18, 20, 22-27, 30-45, 47-48, 80-83, 85-86, 88-96, 98, and 100 should be withdrawn for this additional reason.

The Office Action went on to reject claims 19-21, 43-44, 46, 84, and 99 under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of DiLorenzo (referred to in the Office Action as "the modified Bourgeois et al."). The Office Action rejected claims 10-13 and 87 under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of DiLorenzo, and further in view of U.S. Patent 6,398,728 (Bardy). The Office Action rejected claim 97 under 35 U.S.C. §103(a) as being unpatentable over Bourgeois in view of DiLorenzo, and further in view of U.S. Patent 5,335,657 (Terry, Jr. et al.).

In response, Applicants note that none of these rejections cites any further teaching that would remedy the shortcomings of Bourgeois and DiLorenzo, as discussed above. Claims 10-13, 19-21, 43-44, 46, 84, 87, 97, and 99 are therefore submitted to be allowable at least for the reasons given above regarding the allowability of base claims 1 and 80. The rejection of claims 10-13, 19-21, 43-44, 46, 84, 87, 97, and 99 should be withdrawn.

To the extent Applicants have not responded to any characterization by the Examiner of the asserted art or of Applicants' claimed subject matter, or to any application by the Examiner of the asserted art to any claimed subject matter, Applicants wish to make clear for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Examiner's characterizations, or any other assertions or statements beyond that provided above is unnecessary. Applicants reserve the right to address in detail any such assertions or statements in future prosecution.

CONCLUSION

For the foregoing reasons, the rejections of claims 1-48 and 80-100 are all submitted to be unsustainable and the application is submitted to be in condition for allowance, the early indication of which is earnestly solicited. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

HOLLINGSWORTH & FUNK, LLC
8009 34th Avenue South, Suite 125
Minneapolis, MN 55425
952.854.2700

Date: July 9, 2008

By: Stephen C. Jensen

Stephen C. Jensen
Reg. No. 35,207